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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/814,123	04/01/2004	Zheng Zhang	571-932	8039
1059	7590	10/18/2005	EXAMINER	
BERESKIN AND PARR 40 KING STREET WEST BOX 401 TORONTO, ON M5H 3Y2 CANADA			PENG, KUO LIANG	
			ART UNIT	PAPER NUMBER
			1712	
DATE MAILED: 10/18/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/814,123

Applicant(s)

ZHANG ET AL.

Examiner

Kuo-Liang Peng

Art Unit

1712

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 8/2/05 Amendment.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-74 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 39 and 62-73 is/are allowed.
- 6) ☒ Claim(s) 1-5, 8-10, 38, 40-45 and 47-61 is/are rejected.
- 7) ☒ Claim(s) 6, 7, 11-37 and 46 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

1. The Applicants' amendment filed on August 2, 2005 was received. Claims 1, 39, 41, 49, 51, 54-57, 59, 62-63 and 68 are amended. Claim 74 is added. Now, Claims 1-74 are pending.

2. In view of Applicants' argument, double patenting rejection in the previous Office Action (Paper No. 0405) is/are removed because as indicated in Applicants Remarks (page 17, 4th paragraph), Applicants do not intend to respond to the Office action related to co-pending Application No. 10/647,174. Indeed, this co-pending application has been abandoned for failure to respond the corresponding Office action.

3. Claim objection(s) in the previous Office Action (Paper No. 0405) is/are removed.

4. Claim rejection(s) under 35 USC 112 in the previous Office Action (Paper No. 0405) is/are removed.

Art Unit: 1712

5. Claim rejection(s) under 35 USC 102(g) in paragraph 8 of the previous Office Action (Paper No. 0405) is/are removed.

6. The text of those sections of Title 35, U.S. code not included in this action can be found in a prior Office Action (Paper No. 0405).

Claim Objections

7. Claims 18 and 20 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claims 18 and 20 recite glycerol, propylene glycol and/or trimethylene glycol that are not supported in Claim 17.

Claim Rejections - 35 USC § 102

8. Rejection of Claims 40, 48 and 50 under 35 USC 102(b) as being anticipated by Gill2001 (Chem. Mater. (2001), 13, pages 3404-3421) is maintained because the rejection is adequately set forth in paragraph 9 of Paper No. 0405. Applicant's

Art Unit: 1712

arguments have been fully considered but they are not persuasive. The focus argument related to the core patentability is discussed below.

For Applicants' argument (Remarks, page 20), note that as mentioned in the previous Office action, clearly Gill2001 discloses a siliceous material prepared by hydrolysis/condensation of a poly(glyceryl silicate) in the presence of water-soluble polymers to form a templated sol-gel bioencapsulate or an interpenetrating polymer network. Gill2001' poly(glyceryl silicate) is an intermediate when Applicants' polyol silane precursor is partially hydrolyzed/condensed. However, the instant claims are product-by-process claims. "Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process" In re Thorpe, 777 F. 2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

Claim Rejections - 35 USC § 103

9. Rejection of Claims 1-5, 8-10, 38, 40-45 and 47-48 under 35 USC 103(a) as being unpatentable over Nakanishi688 (US 5 009 688) in view of Gill (J. Am.

Art Unit: 1712

Chem. Soc., (1998), 120, 8587-8598) is maintained because the rejection is adequately set forth in paragraph 11 of Paper No. 0405. Applicant's arguments have been fully considered but they are not persuasive. The focus argument related to the core patentability is discussed below.

For Applicants' argument (Remarks, page 21, 4th paragraph to page 22, paragraph 2 and page 23, 2nd paragraph to page 24, whole page), as mentioned in the previous Office action, Gill teaches that by replacing the alkoxysilyl group wherein the alkoxy is a residue of a monool such as methanol, ethanol with an alkoxysilyl group wherein the alkoxy is a residue of a polyol such as glycerol, the resulting sol-gel material possesses far better properties. (Abstract) Furthermore, during hydrolysis, polyol such as glycerol is liberated, which is less deleterious to bioactivity of the siliceous materials. It also causes less shrinkages and less pore collapse as compared to the typical silicone alkoxide such as silicone methoxide or silicone ethoxide during xerogel formation. (page 8588, left column, 2nd paragraph) In light of the benefit mentioned, it would have been obvious to one of ordinary skill in the art at the time of invention to utilize a silicone glyceryloxide in Nakanishi688's method. Especially, Gill is in the same field as that of Nakanishi688's endeavor. Although Gill does not explicitly teaches the use of Applicants' polyol silane precursor, as mentioned above, Gill does teach the

Art Unit: 1712

advantage of using glyceryl groups as compared to lower alkyloxy groups for making sol-gel product. Furthermore, note that Gill's poly(glyceryl silicate) is an intermediate when Applicants' polyol silane precursor is partially hydrolyzed/condensed. Therefore, one of ordinary skill in the art would know to replace Nakanishi688's lower alkoxy groups with glycerol groups. See MPEP 2144.01.

For Applicants' argument (Remarks, page 22, paragraph 3 to page 23, paragraph 1), although Nakanishi688 teaches the metal oxide preferably has alkoxides containing small number of carbon atoms, this is merely a preferred embodiment. Nakanishi688 certainly does not teach away a metal oxide with alkoxides containing larger number of carbon atoms.

10. Rejection of Claims 1-5, 8-10, 40-45, 47-52, 54-55 and 56 under 35 USC 103(a) as being unpatentable over Nakanishi875 (US 5 624 875) in view of Gill (J. Am. Chem. Soc., (1998), 120, 8587-8598) is maintained because the rejection is adequately set forth in paragraph 12 of Paper No. 0405. Applicant's arguments have been fully considered but they are not persuasive. The focus argument related to the core patentability is discussed below.

For Applicants' argument (Remarks, page 26, 1st paragraph to 3rd paragraph and page 27, 2nd paragraph to page 29, 1st paragraph), as mentioned in the previous Office action, Gill teaches that by replacing the alkoxysilyl group wherein the alkoxy is a residue of a monool such as methanol, ethanol with an alkoxysilyl group wherein the alkoxy is a residue of a polyol such as glycerol, the resulting sol-gel material possesses far better properties. (Abstract) Furthermore, during hydrolysis, polyol such as glycerol is liberated, which is less deleterious to bioactivity of the siliceous materials. It also causes less shrinkages and less pore collapse as compared to the typical silicone alkoxide such as silicone methoxide or silicone ethoxide during xerogel formation. (page 8588, left column, 2nd paragraph) In light of the benefit mentioned, it would have been obvious to one of ordinary skill in the art at the time of invention to utilize a silicone glyceryloxide in Nakanishi875's method. Especially, Gill is in the same field as that of Nakanishi875's endeavor, and Nakanishi875 recognizes the importance of the pore size control. Although Gill does not explicitly teaches the use of Applicants' polyol silane precursor, as mentioned above, Gill does teach the advantage of using glyceryl groups as compared to lower alkyloxy groups for making sol-gel product. Furthermore, note that Gill's poly(glyceryl silicate) is an intermediate when Applicants' polyol silane precursor is partially hydrolyzed/condensed. Especially,

Art Unit: 1712

Nakanishi875 teaches that glycerol gives the best result among other polyols as components for the pore-forming phase. (col. 5, lines 57-60), and when a silane containing glyceryl is used in Nakanishi875's method, during hydrolysis/condensation, the desirable glycerol will be liberated. Therefore, in view of the various advantages mentioned above, one of ordinary skill in the art would know to replace Nakanishi875's lower alkoxy groups with glycerol groups. See MPEP 2144.01. Although Nakanishi875 teaches, "Silicon alkoxides which are desirable in the preparation of the gel are tetramethoxysilane, tetraethoxysilane and polymerized derivatives of these compounds". However, this is merely a preferred embodiment. Nakanishi875 certainly does not teach away a silicon oxide with alkoxides containing larger number of carbon atoms.

For Applicants' argument (Remarks, page 26, 2nd paragraph to page 27, 1st paragraph), Applicants allege that Nakanishi875's "liquids" should not be compatible with the entrapment of sensitive biomolecules. However, it is merely Applicants' opinion, and there is no evidence provided. The arguments of counsel cannot take the place of evidence in the record. *In re Schulze*, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965); *In re Geisler*, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997) Furthermore, Applicants allege that the method for making a meso/macroporous silica monolith of the present invention (i.e., Claim 47 and 48)

Art Unit: 1712

does not include a step of Nakanishi875's step of b) (col. 3, lines 37-38).

However, this argument is inconsistent with the term "comprising" set forth in Claim 41. In addition, the argument of the suitability of Nakanishi875's "liquid" for sensitive biomolecules is irrelevant because it is not claimed in the instant claims.

11. Rejection of Claim 38 is under 35 USC 103(a) as being unpatentable over Nakanishi875 in view of Gill and as evidenced by Barkin (US 3 374 103) is maintained because the rejection is adequately set forth in paragraph 13 of Paper No. 0405.

For Applicants' argument (Remarks, page 29, 2nd paragraph to 5th paragraph), note that Examiner's position is described in previous paragraph.

12. The indicated allowability of Claims 53 and 57-61 is withdrawn in view of a new ground rejection to Nakanishi875 (US 5 624 875) in view of Gill (J. Am. Chem. Soc., (1998), 120, 8587-8598). Rejection based on the new ground rejection follows.

As mentioned in the previous Office action, Nakanishi875 in view of Gill discloses a method for producing chromatography column, (bio)sensor,

Art Unit: 1712

(bio)reactor, etc. Furthermore, note that Gill teaches that the silicate formed is biocompatible which can be used for encapsulating biomolecules. (pages 8587-8588 and 8590-8591) Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention was made to encapsulate Gill's biomolecules in Nakanishi875 in view of Gill's matrix.

13. Claims 6-7, 11-17, 19, 21-37, 46 and 74 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

14. Claims 18 and 20 would be allowable if rewritten to overcome claim objection, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Allowable Subject Matter

15. Claims 39 and 62-73 are allowed.

16. The following is an examiner's statement of reasons for allowance:

None of the above references, taken alone or in combination, teaches or fairly suggests the use of a compound of Formula I set forth in the present invention.

17. The following references cited in PTO-1449 form filed on August 22, 2005 have only been considered to the extent disclosed in the CA abstracts provided by Applicants because Applicants do not provide the corresponding full documents and, if applicable, the English translations thereof.


CH 327722 (CA 53:4001), DE 1136114 (CA 57:62506), Nakanishi, et al., (Reference 13, page 3), Tanaka et al., (Reference 14, page 3), Voronkov et al., (Reference 16, page 4), Muller, et al., (Reference 18, page 4), Sattler et al., (Reference 22, page 4), Hahn (Reference 32, page 5), Voronkov et al., (Reference 33, page 5), Kuznetsova et al., (Reference 34, page 5) and Kopylov et al., (Reference 35, page 5)

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kuo-Liang Peng whose telephone number is (571) 272-1091. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM. If attempts to reach the examiner by telephone are

Art Unit: 1712

unsuccessful, the examiner's supervisor, Randy Gulakowski, can be reached on (571) 272-1302. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

klp
October 15, 2005


Kuo-Liang Peng
Primary Examiner
Art Unit 1712